

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
27 May 2004 (27.05.2004)

PCT

(10) International Publication Number  
**WO 2004/044170 A3**

(51) International Patent Classification<sup>7</sup>: **C07H 21/04**,  
C12Q 1/68

RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR,  
TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(21) International Application Number:  
PCT/US2003/036131

(84) Designated States (*regional*): ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(22) International Filing Date:  
13 November 2003 (13.11.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
60/425,968 13 November 2002 (13.11.2002) US

(71) Applicant (*for all designated States except US*):  
**METABOLEX, INC.** [US/US]; 3876 Bay Center Place,  
Hayward, CA 94545 (US).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **JOHNSON, Jeffrey, D.** [US/US]; 15 Corte Mateo, Moraga, CA 94556 (US). **PALMA, John, F.** [US/US]; 2567 Craneford Way, San Ramon, CA 94583 (US). **SCHWEITZER, Anthony, C.** [US/US]; P.O. Box 2341, Menlo Park, CA 94026 (US). **BLUME, John, E.** [US/US]; 31 St. Maurice Court, Danville, CA 94526 (US).

(74) Agents: **HINSCH, Matthew, E.** et al.; Townsend and Townsend and Crew LLP, Two Embarcadero Center, 8th Floor, San Francisco, CA 94111-3834 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT,

**Declarations under Rule 4.17:**

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations*
- *of inventorship (Rule 4.17(iv)) for US only*

**Published:**

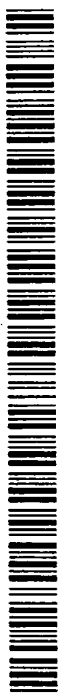
- *with international search report*

(88) Date of publication of the international search report:  
13 January 2005

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: A PANCREATIC ISLET TRANSCRIPTION FACTOR AND USES THEREOF

(57) Abstract: The present invention provides a pancreatic islet transcription factor and methods of treating and diagnosing diabetes.



WO 2004/044170 A3

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/36131

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C07H 21/04; C12Q 1/68  
US CL : 536 23.1, 24.3, 24.33; 435/6

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 536 23.1, 24.3, 24.33; 435/6

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
Please See Continuation Sheet

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	COLLINS FRANCIS. Generation and initial analysis of more than 15,000 full-length human and mouse cDNA sequences. Proceeding of the National Academy of Science. Vol. 99, No. 26, pages 16899-16903, 24 December 2002.	1-3

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

\* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search

17 August 2004 (17.08.2004)

Date of mailing of the international search report

26 OCT 2004

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Cynthia B. Wilder, Ph.D.

Telephone No. (703) 308 0196

*Janice Ford*  
*for*

## INTERNATIONAL SEARCH REPORT

PCT/US03/36131

### BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-6, 11-17 and 32-40, drawn to an isolated nucleic acid and method of making and using.

Group II, claim(s) 7-9, drawn to polypeptide.

Group III, claim(s) 10, drawn to antibody.

Group IV, claim(s) 18-27, drawn to ligand binding assay.

Group V, claim(s) 28-31, drawn to method of treating.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The claims of Groups I-V lack a special technical feature that is the same or that corresponds to a special feature. Likewise there is not a special technical feature linking the recited groups, as would be necessary to fulfill the requirements for unity of invention. The special technical feature of the invention of Group I is an isolated nucleic acid and gene and method of making and using said nucleic acid. The nucleic acid of the Group I is composed of nucleotides and function in hybridization and amplification procedures for diagnosing a subject with diabetes. The special technical feature of Group II is an isolated polypeptide comprised of amino acid that may be utilized in western blotting experiments. The special technical feature of Group III is an antibody is composed of amino acids fused via peptide linkage which may used in binding assays or as a treatment regiment. The special technical feature of Group IV is drawn to a ligand-binding assay for diagnosing diabetes. The special technical feature of Group V is drawn to a method of treating diabetic or pre-diabetic animals. None of these special technical features are common to the other groups, nor do they correspond to a special technical feature in the other groups. Therefore, unity of invention is lacking.

### Continuation of B. FIELDS SEARCHED Item 3:

GENSEQ, GENEMBL, EST, PUBLISHED APPLICATION, SWISSPROT\_42, SPTREMBL\_25, ISSUED PATENTS, PUR\_78